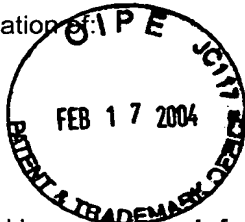


ASSISTANT COMMISSIONER FOR PATENTS  
Alexandria, VA 22313-1450

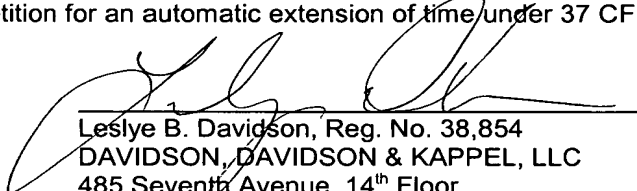
In re application of:   
Serial No.:  
Filed:  
For:

John Nicholas STANIFORTH  
10/677,847  
October 2, 2003  
**PHARMACEUTICAL SUPERDISINTEGRANT**

Sir:

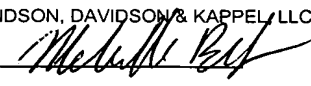
Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.
- ☐ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
- ☒ No fee for additional claims is required.
- ☐ A filing fee for additional claims calculated as shown below, is required:
- ☒ Also transmitted herewith are:
- ☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)
- ☒ Other: **-Form PTO-1449 (3 sheets)**
- ☐ Check(s) in the amount of **\$00. 00** is/are attached to cover:
- ☐ Filing fee for additional claims under 37 C.F.R. 1.16
- ☐ Petition fee for extension under 37 C.F.R. 1.136
- ☐ Other:
- ☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
- ☐ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☐ Any patent application processing fees under 37 C.F.R. 1.17.
- ☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
Leslie B. Davidson, Reg. No. 38,854  
DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
Tel: (212) 736-1940  
Fax: (212) 736-2427

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on February 12, 2004.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: 



541.1027CON

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: John Nicholas STANIFORTH  
Serial No.: 10/677,847  
Filed: October 2, 2003  
For: **Pharmaceutical Superdisintegrant**  
Art Unit: 1615

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Alexandria, VA 22313-1450

February 12, 2004

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (3 Sheets), enclosed herewith, for consideration by the Examiner in connection with the examination of the above-identified patent application.

The references cited on the enclosed Form PTO-1449, are of record in the Parent U.S. Application Serial No. 09/731,238. Accordingly, under 37 C.F.R. § 1.98(d), copies of these references are not enclosed.

The Examiner's attention is directed to sheet 3 of the enclosed Form PTO-1449, which lists references cited by the Examiner during prosecution of the Parent U.S. Application Serial No. 09/731,238. Accordingly, under 37 C.F.R. § 1.98(d), copies of these references are not enclosed.

Applicants also respectfully advise the Examiner of the following commonly assigned U.S. Patents and applications:

U.S. Patent No. 5,585,115, "Pharmaceutical Excipient Having Improved Compressibility," issued December 17, 1996;

U.S. Patent No. 5,725,884, "Pharmaceutical Excipient Having Improved Compressibility," issued March 10, 1998;

U.S. Patent No. 6,103,219, "Pharmaceutical Excipient Having Improved Compressibility," issued August 15, 2000;

U.S. Patent No. 6,217,909, "Pharmaceutical Excipient Having Improved Compressibility," issued April 17, 2001;

U.S. Patent No. 5,725,883, "Pharmaceutical Excipient Having Improved Compressibility," issued March 10, 1998;

U.S. Patent No. 5,866,166, "Pharmaceutical Excipient Having Improved Compressibility," issued February 2, 1999;

U.S. Patent No. 6,106,865, "Pharmaceutical Excipient Having Improved Compressibility," issued August 22, 2000;

U.S. Patent No. 5,733,578, "Directly Compressible High Load Acetaminophen Formulations," issued March 31, 1998;

U.S. Patent No. 5,965,166, "Directly Compressible High Load Acetaminophen Formulations," issued October 22, 1999;

U.S. Patent No. 6,217,907, "Directly Compressible High Load Acetaminophen Formulations," issued April 17, 2001;

U.S. Patent No. 5,741,524, "Sustained Release Formulations Prepared With Modified Microcrystalline Cellulose," issued April 21, 1998;

U.S. Patent No. 5,858,412, "Sustained Release Formulations Prepared With Modified Microcrystalline Cellulose," issued January 12, 1999;

U.S. Patent No. 6,395,303, "Process For Preparing Pharmaceutical Process," issued May 28, 2002;

U.S. Patent No. 5,948,438, "Pharmaceutical Formulations Having Improved Disintegration And/Or Absorptivity," issued September 7, 1999;

U.S. Patent No. 6,471,994, "Pharmaceutical Excipient Having Improved Compressibility," issued October 29, 2002;

US Patent No. 6,660,303B2, "Pharmaceutical Superdisintegrant," issued December 9, 2003; and

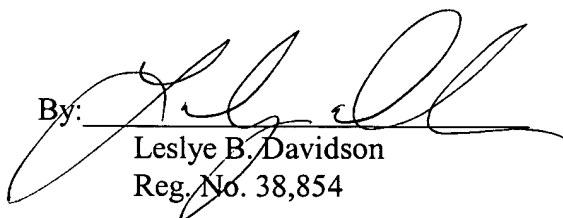
U.S. Patent Application Serial No. 09/384,829, "Pharmaceutical Excipient Having Improved Compressibility," filed August 27, 1999, abandoned.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy be promptly forwarded.

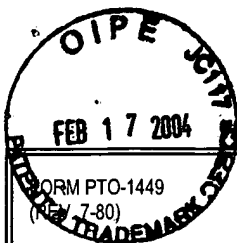
No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. § 1.97(b), before the mailing of a first Office Action on the merits. If any fee is deemed to be due, the Commissioner is hereby authorized to charge such fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By:   
Leslye B. Davidson  
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FORM PTO-1449  
(Rev. 7-80)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:  
541.1027CON

SERIAL NO.:  
10/677,847

**LIST OF PRIOR ART CITED BY APPLICANT**

(Use several sheets if necessary)

APPLICANT(S): John STANIFORTH

FILING DATE:  
October 02, 2003

GROUP:  
To be assigned

**U.S. PATENT DOCUMENTS**

| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | NAME              | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|----|-----------------|---|---|---|---|---|---|----------|-------------------|-------|----------|-------------------------------|
|                      | AA | 3               | 1 | 4 | 1 | 8 | 7 | 5 | 07/21/64 | Battista et al.   | 260   | 212      | 03/15/61                      |
|                      | AB | 5               | 2 | 7 | 2 | 1 | 9 | 1 | 12/21/93 | Ibrahim et al.    | 524   | 35       | 08/21/91                      |
|                      | AC | 5               | 4 | 5 | 6 | 9 | 2 | 1 | 10/10/95 | Mateescu et al.   | 424   | 465      | 02/09/94                      |
|                      | AD | 5               | 5 | 8 | 5 | 1 | 1 | 5 | 12/17/96 | Sherwood et al.   | 424   | 489      | 01/09/95                      |
|                      | AE | 5               | 7 | 2 | 5 | 8 | 8 | 3 | 03/10/98 | Staniforth et al. | 424   | 489      | 06/07/95                      |
|                      | AF | 5               | 7 | 2 | 5 | 8 | 8 | 4 | 03/10/98 | Sherwood et al.   | 424   | 489      | 09/30/96                      |
|                      | AG | 5               | 7 | 3 | 3 | 5 | 7 | 8 | 03/31/98 | Hunter et al.     | 424   | 489      | 11/15/95                      |
|                      | AH | 5               | 7 | 4 | 1 | 5 | 2 | 4 | 04/21/98 | Staniforth et al. | 424   | 489      | 07/08/96                      |
|                      | AI | 5               | 8 | 5 | 8 | 4 | 1 | 2 | 01/12/99 | Staniforth et al. | 424   | 489      | 12/17/97                      |
|                      | AJ | 5               | 8 | 6 | 6 | 1 | 6 | 6 | 02/02/99 | Staniforth et al. | 424   | 489      | 06/10/96                      |
|                      | AK | 5               | 9 | 4 | 8 | 4 | 3 | 8 | 09/07/99 | Staniforth et al. | 424   | 464      | 06/04/97                      |
|                      | AL | 5               | 9 | 6 | 5 | 1 | 6 | 6 | 10/12/99 | Hunter et al.     | 424   | 489      | 11/05/97                      |
|                      | AM | 5               | 9 | 8 | 9 | 5 | 8 | 9 | 11/23/99 | Cartilier et al.  | 424   | 465      | 10/24/97                      |
|                      | AN | 6               | 1 | 0 | 3 | 2 | 1 | 9 | 08/15/00 | Sherwood et al.   | 424   | 49       | 12/17/97                      |
|                      | AO | 6               | 1 | 0 | 6 | 8 | 6 | 5 | 08/22/00 | Staniforth et al. | 424   | 489      | 03/10/98                      |

**FOREIGN PATENT DOCUMENTS**

|  |    | DOCUMENT NUMBER |    |   |   |   |   |   | DATE      | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|----|-----------------|----|---|---|---|---|---|-----------|---------|-------|----------|-------------|----|
|  |    |                 |    |   |   |   |   |   |           |         |       |          | YES         | NO |
|  | AP |                 | 94 | 0 | 2 | 1 | 2 | 1 | 3 Feb 94  | WO      | A61K  | 9/22     |             |    |
|  | AQ |                 | 94 | 2 | 1 | 2 | 3 | 6 | 29 Sep 94 | WO      | A61K  | 9/20     |             |    |
|  | AR |                 |    |   |   |   |   |   |           |         |       |          |             |    |

**OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

|          |                 |  |
|----------|-----------------|--|
|          | AS              |  |
| EXAMINER | DATE CONSIDERED |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-144  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: 541.1027CON

SERIAL NO.:  
10/677,847

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): John STANIFORTH

FILING DATE: October 02, 2003

GROUP:  
To be assigned

## U.S. PATENT DOCUMENTS

| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE     | NAME              | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|----|-----------------|---|---|---|---|---|---|----------|-------------------|-------|----------|-------------------------------|
|                      | AA | 4               | 2 | 2 | 6 | 8 | 4 | 8 | 10/07/80 | Nagai, et al.     | 424   | 19       |                               |
|                      | AB | 4               | 7 | 7 | 2 | 4 | 7 | 3 | 09/20/88 | Patel et al.      | 424   | 457      |                               |
|                      | AC | 5               | 1 | 0 | 8 | 7 | 5 | 7 | 04/28/92 | Erdos et al.      | 424   | 451      |                               |
|                      | AD | 5               | 2 | 7 | 5 | 8 | 2 | 4 | 01/04/94 | Carli et al.      | 424   | 488      |                               |
|                      | AE | 5               | 5 | 9 | 9 | 5 | 5 | 5 | 02/04/97 | El-Nokaly         | 424   | 490      |                               |
|                      | AF | 6               | 2 | 1 | 7 | 9 | 0 | 9 | 04/17/01 | Sherwood et al.   | 424   | 494      |                               |
|                      | AG | 6               | 2 | 1 | 7 | 9 | 0 | 7 | 04/17/01 | Hunter et al.     | 424   | 489      |                               |
|                      | AH | 6               | 3 | 9 | 5 | 3 | 0 | 3 | 05/28/02 | Staniforth et al. | 424   | 499      |                               |
|                      | AI | 6               | 4 | 7 | 1 | 9 | 9 | 4 | 10/29/02 | Staniforth et al. | 424   | 489      |                               |
|                      | AJ | 6               | 6 | 6 | 0 | 3 | 0 | 3 | 12/09/03 | Staniforth        | 424   | 489      |                               |
|                      | AK |                 |   |   |   |   |   |   |          |                   |       |          |                               |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER |  |  |  |  |  |  | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|----|-----------------|--|--|--|--|--|--|------|---------|-------|----------|-------------|----|
|  |    |                 |  |  |  |  |  |  |      |         |       |          | YES         | NO |
|  | AL |                 |  |  |  |  |  |  |      |         |       |          |             |    |
|  | AM |                 |  |  |  |  |  |  |      |         |       |          |             |    |
|  | AN |                 |  |  |  |  |  |  |      |         |       |          |             |    |
|  | AO |                 |  |  |  |  |  |  |      |         |       |          |             |    |
|  | AP |                 |  |  |  |  |  |  |      |         |       |          |             |    |

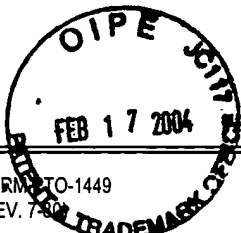
## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.


 FORM TO-1449  
(REV. 7-99)
U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
541.1027CONSERIAL NO.:  
10/677,847

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): John STANIFORTH

FILING DATE:  
October 02, 2003GROUP:  
To be assigned

## U.S. PATENT DOCUMENTS

| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   |  | DATE     | NAME              | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|----|-----------------|---|---|---|---|---|---|--|----------|-------------------|-------|----------|-------------------------------|
|                      | BA | 5               | 4 | 6 | 8 | 2 | 8 | 6 |  | 11/21/95 | Wai-Chun et al.   | 106   | 210      | 09/30/94                      |
|                      | B  | 4               | 9 | 1 | 0 | 0 | 2 | 3 |  | 03/20/90 | Botzolakis et al. | 424   | 470      | 06/09/88                      |
|                      | C  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | D  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | E  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | F  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | G  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | H  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | I  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | J  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |
|                      | K  |                 |   |   |   |   |   |   |  |          |                   |       |          |                               |

## FOREIGN PATENT DOCUMENTS

|  |   | DOCUMENT NUMBER |  |  |  |  |  |  |  | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|--|---|-----------------|--|--|--|--|--|--|--|------|---------|-------|----------|-------------|----|
|  |   |                 |  |  |  |  |  |  |  |      |         |       |          | YES         | NO |
|  | L |                 |  |  |  |  |  |  |  |      |         |       |          |             |    |
|  | M |                 |  |  |  |  |  |  |  |      |         |       |          |             |    |
|  | N |                 |  |  |  |  |  |  |  |      |         |       |          |             |    |
|  | O |                 |  |  |  |  |  |  |  |      |         |       |          |             |    |
|  | P |                 |  |  |  |  |  |  |  |      |         |       |          |             |    |

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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|--|---|--|
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EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.